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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/558,260	04/25/2000	David W. Cunningham		8995

7590 02/13/2004

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EXAMINER	
PORTER, RACHEL L	
ART UNIT	**PAPER NUMBER**
3626	

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/558,260	CUNNINGHAM, DAVID W.	
	Examiner	Art Unit	
	Rachel L. Porter	3626	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 16-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-10* is/are allowed.

6)☒ Claim(s) *11-14 and 16-31* is/are rejected.

7)☒ Claim(s) *32-42* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 11/17/03. Claims 1-14 and 16-42 are pending. Claims 29-42 are new.

2. The information disclosure statement filed June 23, 2000 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language (German Document No. DE431194A1). It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 101

3. The rejection of claims 11,13 and 16-22 under 35 U.S.C. 101 is hereby withdrawn due to the amendment filed 11/17/03.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 29-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 recites that "upon actuation the database identifies that the state...has changed..." It is unclear how the term "actuation" relates to the context of the current claim language. The Examiner understands the term "actuation" to refer to the mechanical action or motion of an object. However, it is not clear what object is "actuated" in the current claim. Moreover, the Examiner is unable to find support for the term "actuation" in the originally filed disclosure to provide context or meaning to the term. For the purpose of applying art, the Examiner will interpret this term to refer to the activation of the pharmaceutical product media described in claim 12. For consistency, the Examiner suggests that the same be term be used to refer to the step or action throughout the claim language.

Claims 30-31 inherit the deficiencies of claim 29 through dependency, and are also rejected.

Allowable Subject Matter

6. Claims 1-10 are allowed.

7. Claim 32 appears to be cancelled claim 15 rewritten in independent form including all of the limitations of the base claim and the intervening claim(s). However, claim 32 is objected to because of the following informalities: step(f) recites "...validating the pharmaceutical product media prior to filing the prescription...", while the limitation previously recited that the validating the media prior to fulfilling the prescription. Appropriate correction required.

Claims 32-42 would be allowable if rewritten to overcome the objection to claim 32 provided above.

8. The following is a statement of reasons for the indication of allowable subject matter: Claims 1 and 32 are drawn toward a method of activating and validating pharmaceutical product media by communicatively linking the media to a central computing station. The closest prior art of record does not teach or fairly suggest the combined steps of: 1) activating the pharmaceutical product media prior to issuing the media to a patient, wherein the activation by the prescriber includes the prescriber communicatively linking the media to a central computing station which records encoded information from the media into a database associated with the central computing station; and 2) validating the product media, wherein validation by the pharmacy includes communicatively linking the presented pharmaceutical product media with the central computing station to determine if the pharmaceutical product media has been activated by a prescriber. Dependent claims 2-8 and 33-42 incorporate the allowable features of claim 1 and claim 32 respectively, are equally allowable.

Similarly, claim 9 is drawn toward a system, which controls and tracks the transfer of pharmaceutical product media and the pharmaceutical product. The closest prior art of record does not disclose: prescriber terminals and pharmacy terminals receiving and reading data encoded on pharmaceutical product media assuming the form of individual product media slips and communicating that data to the central computing station to track and control the movement of pharmaceutical product media slips and the dispensing of a pharmaceutical product identified by the individual

pharmaceutical product media slips. Dependent claim 10 incorporates the allowable features of claim 9 and is equally allowable.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claim 11-14, and 16-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lapsker (USPN 4,971,362) in view of Wolff et al (USPN 5,671,282).

Claim 11) Lapsker teaches a method of prescribing and dispensing prescription pharmaceutical products comprising:

- forming a pharmaceutical product media and encoding that media with information that identifies one or more particular prescription pharmaceutical products (Lapsker: col. 4, lines 10-45)
- issuing the pharmaceutical product media to one or more prescribers;(col. 4, lines 10-49)
- activating the pharmaceutical media and transferring the activated pharmaceutical product media from the prescriber to the patient, wherein the activated pharmaceutical product media identifies one or more prescription pharmaceutical products that have been prescribed by the prescriber for the patient; and (Lapsker: col. 4, lines 50-59; col. 5, lines 46-53)

- presenting the activated pharmaceutical product media to a pharmacy that fills the prescription identified by the pharmaceutical product media (Lapsker: col. 6, lines 14-32)

Lapsker discloses the method of claim 11, as explained above including the step of activating pharmaceutical media (e.g. signing), but does not expressly disclose that the activating is performed electronically. Wolff discloses a method wherein prescribers generate electronic and paper prescriptions (i.e. pharmaceutical product media) (col. 5, lines 32-60; col. 7, lines 20-54). Moreover, Wolff further discloses that prescriptions include the signature of the prescriber (col. 1, lines 23-32). It is respectfully submitted that one of ordinary skill in the art would have understood that Wolff reference allows the user to electronically sign (i.e. activate) the pharmaceutical product media. At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to combine the method Lapsker with the method of Wolff to allow the user to generate electronic (and paper) prescriptions (i.e. pharmaceutical product media), which are electronically activated (i.e. signed). One would have been motivated to include this feature to provide a retrievable and reviewable record in order to verify the validity of information in the document (e.g. prescription) as suggested by Wolff (col. 2, lines 13-21).

Claim 12) Lapsker teaches the method of claim 11 further comprising the activation and validation of pharmaceutical product media. (col. 4, lines 50-59; col. 6, lines 14-32) Lapsker further discloses maintaining a database (i.e. pharmacist's records) of the presented pharmaceutical product media issued by a prescriber. (col. 5, lines 3-6; col.

6, lines 14-32—Prescription includes practitioner's identification code. Pharmacist must make note of prescription information and sign that it has been dispensed). However, Lapsker does not expressly disclose electronically activating the pharmaceutical product media by having a prescriber communicatively linking the pharmaceutical product media to a central computing station which records the information from the media into a database associated with the central computing station. Wolff discloses a method wherein a prescription (i.e. pharmaceutical product media) is activated by having a prescriber communicatively linking the pharmaceutical product media to a central computing station which records the information from the media into a database associated with the central computing station. (col. 3, lines 27-col. 4, line 34; col. 5, lines 36-63) Wolff provides human and machine-readable data on the prescription when it is generated (i.e. written by the prescriber) and this data stored by the server subsystem, which includes document storage (i.e. a database associated with the central computing station.) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Lapsker with the teaching of Wolff to activate the prescription (i.e. pharmaceutical product media) by recording information regarding the prescription into a database associated with a central computing station. As suggested by Wolff, one would have been motivated to include this feature to allow the prescription to be tracked and to allow the prescription bearer to demonstrate its authenticity to a third party. (col. 3, lines 27-34)

Claim 13) Lapsker teaches the method of claim 11 wherein the pharmacy validates the media prior to fulfilling the prescription identified thereby (Lapsker: col. 6, lines 14-

31), but does not expressly disclose that the validation step occurs electronically. Wolff teaches a method wherein the pharmacy electronically validates the pharmaceutical product media. (col. 5, line 4-col. 6, line 6; col. 7, lines 21-54) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Lapsker with the teaching of Wolff to allow the pharmacy to electronically validate the pharmaceutical product media (prior to fulfilling the prescription.) As suggested by Wolff, one would have been motivated to include this feature to confirm that the prescription has not already been filled, that no new/conflicting prescriptions have issued to the patient, and to prevent possible future authorizations of the prescription. (col. 7, lines 39-47).

Claim 14) Lapsker teaches the method of claim 11 further comprising the validation of pharmaceutical product media. (col. 4, lines 50-59; col. 6, lines 14-32) Lapsker further maintaining a database (pharmacy records) of the presented pharmaceutical product media issued by a prescriber. (col. 5, lines 3-6; col. 6, lines 14-32—Prescription includes practitioner's identification code. Pharmacist must make note of prescription information and sign that it has been dispensed). However, Lapsker also does not disclose that the media is validated by communicatively linking the presented pharmaceutical product media with a central computing station to determine if the media has been appropriately issued. Wolff teaches a method further comprises validating the product media by communicatively linking the presented media with a central computing station, which determines if the presented media has been issued appropriately by a prescriber. (col 3, line 19-col. 4, line 4; col. 5, lines 4-col. 6, line 42—

e.g. scan paper prescription to check with server subsystem to determine the validity of the prescription) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Lapsker with the method of Wolff to validate the prescription (i.e. media) by linking the media with a central computing station to determine if the prescription was properly issued. As suggested by Wolff, one would have been motivated to include this feature to ensure
the prescription has not already been filled, that no new/conflicting prescriptions have issued to the patient, and to prevent possible future authorizations of the prescription. (col. 7, lines 39-47)

Claim 16) Lapsker teaches the method of claim 11, wherein the pharmaceutical product media includes a plurality of data fields, including at least one data field for identifying at least one prescribed pharmaceutical product, and associated data fields for identifying the quantity and number of refills for the associated prescribed pharmaceutical product. (col. 4, line 39-col. 5, line 2; col. 5, lines 47-61)

Claims 17-18) Lapsker teaches a method wherein the issuing and activation of the media are carried out in separate steps and wherein the steps of issuing, activating, transferring and presenting are carried out in the order set forth. (col. 4, line 11- col. 6, line 32)

Claim 19) Lapsker teaches a method wherein presenting the pharmaceutical product media to the pharmacy and the dispensing of the identified product is conditioned upon the prior activation of the media. (col. 4, lines 46-67; col. 6, lines 14-33)

(Claim 20) Lapsker teaches a method wherein activating the pharmaceutical product media is conditioned upon the prior issuance of the media. (col. 4, lines 50-59; col. 5, lines 11-27)

Claims 21-22) Lapsker teaches a method wherein the media is issued in an inactive state (i.e. without a signature), and wherein in activating the product media it is converted from an inactive to an active state. (col. 4, line 11- col. 6, line 32) Moreover, it is respectfully submitted that the drug dispensary (i.e. pharmacy) must note the signature of the prescribing physician on the prescription leaf and cheque before dispensing the drug. As such, the presenter must present the media in its "activated state" (i.e. with a prescriber's signature) in order to receive the desired drug.

Claim 23) Lapsker teaches a method of claim 11 including storing selected information on the pharmaceutical product media in a database. (col. 6, lines 28-33) The pharmacist stores a copy of the prescription portion of the media in his/her records (i.e. database).

Claim 24) Lapsker teaches a method including recording in the database that a particular media has been activated. (col. 6, lines 11-33) The stored prescription includes the signature of the physician. (i.e. activation of the media)

Claim 25) Lapsker teaches method of claim 24 further including recording information in the database that indicates that the product media has been presented to a pharmacy and that the pharmacy has delivered the pharmaceutical product identified on the media presented. (col. 5, lines 15-36; col. 6, lines 14-41)

Claim 29) Lapsker teaches the method of claim 11 further comprising the activation and validation of pharmaceutical product media. (col. 4, lines 50-59; col. 6, lines 14-32) Lapsker further discloses a method wherein the pharmaceutical product media is inactive before signing (i.e. activation) and wherein a database records (e.g. pharmacy records) if the presented pharmaceutical product media has been appropriately issued by a prescriber. (col. 5, lines 3-6; col. 6, lines 14-32—A prescription is not valid unless signed by a prescriber/physician. The prescription includes practitioner's identification code. Pharmacist must make note of prescription information and sign that it has been dispensed and also stores the written prescription for his/her records). However, Lapsker does not expressly disclose electronically activating the pharmaceutical product media and having the database associated with a central computing station identify the state of the media (i.e. active or inactive).

Wolff discloses a method wherein a prescription (i.e. pharmaceutical product media) is electronically activated and wherein a database associated with a central computing station records all information from the prescription, including the active/inactive state of the prescription (i.e. pharmaceutical product media). (col. 3, lines 27-col. 4, line 34; col. 5, lines 36-63) Wolff provides human and machine-readable data on the prescription when it is generated (i.e. written by the prescriber) and all this data is stored by the document storage of the server subsystem (i.e. a database associated with the central computing station.) Moreover, the Wolff system detects changes in the information included on the issued prescription (col. 8, lines 59-col. 9, line 15). It is submitted that because the Wolff server subsystem records/stores all information found

on the prescription, the Wolff system therefore stores the state of the media (i.e. whether the prescription signed/activated) and notes changes in the state of the prescription (i.e. media).

At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Lapsker with the teaching of Wolff to store information regarding the signed or unsigned (i.e. active or inactive) state of the prescription in a database associated with a central computing station. As suggested by Wolff, one would have been motivated to include this feature to allow the prescription to be tracked and to allow the prescription bearer to demonstrate the authenticity of to a third party. (col. 3, lines 27-34)

Claims 30-31) Lapsker teaches a method wherein the pharmacy validates an activated media prior to fulfilling a prescription (Lapsker: col. 6, lines 14-31), but does not expressly disclose that the validation step occurs electronically. Lapsker further does not expressly disclose that this validation occurs by communicatively linking the presented media with a central computing station that includes a database to determine if the prescription (media) has been appropriately issued. Wolff teaches a method further comprises validating the product media by communicatively linking the presented media with a central computing station, which includes a database (i.e. the document storage section of the server subsystem) (col 3, line 19-col. 4, line 4; col. 5, lines 4-col. 6, line 42). In the Wolff reference this validation determines if a prescriber has issued the presented prescription appropriately. (e.g. signed/ in an "active" state). (col 3, line 19-col. 4, line 4; col. 5, lines 4-col. 6, line 42—e.g. scan paper prescription to

check with server subsystem to determine the validity of the prescription) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Lapsker with the method of Wolff to validate the prescription (i.e. media) by linking the media with a central computing station to determine if the prescription was properly issued. (e.g. is signed/active) As suggested by Wolff, one would have been motivated to include this feature to ensure the prescription has not already been filled, that no new/conflicting prescriptions have issued to the patient, and to prevent possible future authorizations of the prescription. (col. 7, lines 39-47)

11. Claims 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lapsker (USPN 4,971,362) and Wolff as applied to claim 11, and further in view of Edelson et al (USPN 5,737,539).

Claims 26-28) Lapsker and Wolff teach the method of claim 11 including recording information relative to the product media in a database. (col. 6, lines 28-33) Lapsker also discloses that the step of activating includes identifying the product media that the prescriber wants to activate and storing this information in a database. (i.e. the pharmacist's records) (col. 4, line 50-54; col. 5, lines 8-15). Lapsker further discloses that the pharmacist's database records that a particular product identified on the product media has been delivered to the person. (col. 5, lines 28-33; col. 6, lines 32). However, Lapsker and Wolff do not expressly disclose that the database has communication links to a series of prescribers and a series of pharmacies. Edelson discloses a method that provides a database that records prescription entry and prescription fulfillment information and is accessible to a series of prescribers (i.e. point-of care) and to a

series of pharmacies. (col. 26, line 55-col. 28, line 7). Thus, Edelson provides links between the prescribers and the database and a series of pharmacies and the database. At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to further modify the method of Lapsker and Wolff with the teachings of Edelson to record information regarding the status of prescriptions in a database accessible to prescribers and pharmacies. As suggested by Edelson, one would have been motivated to do this to ensure that prescriptions have not been filled multiple times and thereby avoid system abuse. (col. 27, line 30-43)

Response to Arguments

(A) On page 12 of the response filed 11/17/03, the Applicant argues issues regarding the rejection of claims 11,13, and 16-22 under 35 U.S.C. 101.

In response, the claims have been amended to recite the use of technological arts in steps of the body of the claim. Thus, the amendment to the claims overcome the rejection provided in the previous Office Action, Paper No. 7, and the 101 rejection has been withdrawn.

(B) On page 14 of the response filed 11/17/03, the Applicant argues the rejection of claims 11 and 13 under 35 U.S.C. 102 based upon the Lapsker reference.

In response, the present claims have been amended to incorporate newly added limitations. Consequently, a new combination of references of references has been applied to address the amended claim language.

(C) On pages 14-16 of the 11/17/03 response, the Applicant argues the combination of Lapsker and Edelson.

In response, a new combination of references has been provided to address the amendments and new claim limitations included in Applicant's 11/17/03 response.

(D) On pages 16-17, the Applicant apparently argues that Lapsker teaches away from any electronic/automated modification. The Applicant further argues that "the beauty of the Lapsker invention is that it is a paper system-easy to use and quite economical- and does not require the pharmacist and the doctors to purchase and implement expensive computerized systems."

In response, the Examiner understands the Lapsker reference is a paper prescription pad, but respectfully disagrees with the Applicant's summary of the limited usefulness and applicability of the disclosed invention. The background of the invention describes a plurality of existing problems that the Lapsker invention was intended to overcome. These problems include difficulty in tracking the distribution of pharmaceutical vouchers by physicians and the inconvenience of record keeping for pharmacists (col. 2, lines 25-42). At the time of the Applicant's invention, one of ordinary skill in the art would have understood that the use computers and automation (e.g. in the Wolff reference) in combination with the Lapsker invention would not destroy the primary reference. On the contrary, such a modification would further Lapsker's ability to overcome previous limitations in the prior art by providing additional means for controlling and monitoring the dispensing of (free) pharmaceutical products and dosages using vouchers. (Lapsker: col. 2, lines 52-60)

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel L. Porter whose telephone number is 703-305-0108. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (703)305-9588. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-1113.

RP
RP
February 7, 2004

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER
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